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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,965	06/20/2006	Ezio Bombardelli	2503-1189	7314

466 7590 06/30/2009

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EXAMINER	
ML QIUWEN	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
06/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,965	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10 and 13* is/are pending in the application.

4a) Of the above claim(s) *3,6-8 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,9 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 5/29/09 is acknowledged, with the cancellation of Claims 5, and 11-12. Claims 1-4, 6-10, and 13 are pending. Claims 3, 6-8, and 10 are withdrawn as they are directed toward a non-elected invention groups or species.

Claims 1, 2, 4, 9, and 13 are examined on the merits.

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 9, and 13 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13 recite "icarin derivatives" (line 8). The phrase "icarin derivatives" is unclear. It is unclear what modifications of the icarin would be encompassed in the icarin derivatives. The icarin derivatives can be any structure, and any modification. Thus, it is unclear what modifications and derivatives are encompassed by the claimed icarin derivatives. Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 9, and 13 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Di Pierro (WO 02/098436 A1), in view of Bertini Curri et al (US 5,176,919), and further in view of Smith, III et al (US 2003/0069618).

Di Pierro discloses a pharmaceutical and/or cosmetic composition for the treatment of cellulite comprising 0.1-2.5% complex of escin/beta-siterol with phospholipids (the third vasoactive agent, thus overlaps with the claimed range of 0.5-2%), 0.1-2.5% complex of *Gingko biloba* dimeric flavonoids with phospholipids (the second vasoactive agent, thus overlaps with the claimed range of 0.1-1%) etc (page 2, lines 20-28). Di Pierro also teaches that the complex of escin/beta-sitosterol with phospholipids has the same action as escin, but shows a more prolonged release of the active principles and improved bioavailability (page 3, lines 10-13); and the complex of *Gingko biloba* dimeric flavonoids with phospholipids, has the same activity as the dimeric *Gingko biloba* flavones in the free form, but shows a more prolonged release of the active principles and better bioavailability. *Gingko biloba* dimeric flavonoids are extremely

potent vasoactive agents due to their inhibitory action on the release of histamine and of the enzyme cAMP phosphodiesterase from mast cells (page 3, liens 13-20). Di Pierro further teaches that the composition of the invention will be formulated in the form of cream, oil, gel, foam, emulsion, milk (page 4, lines 15-20).

Di Pierro does not teach the incorporation of the first vasoactive agent visnadin, or the claimed amount of visnadin into the composition.

Bertini Curri et al teach pharmaceutical and cosmetic compositions comprising extracts of Ammi visnaga and Ammi majus containing visnadine (the same as visnadin) and/or visnadine-like coumarins and flavoncoumarols, or visnadine itself in purified form, for the cosmetic treatment of defects due to insufficient blood perfusion of the skin and of the subcutaneous adipose tissue, particularly for the treatment of precocious senile involution of the face and neck skin, cellulitis, cutaneous stretch marks, alopecias and similar conditions (col 2, lines 10-25). Bertini Curri et al also teach the composition is a cream, ointment, gel or lotion (claim 5). Bertini Curri et al further teach a gel containing 1% of visnadine as active principle (1 g of visnadine out of a 100 g gel) (thus falls into the claimed range of 0.05-2% for the first vasoactive agent).

Smith, III et al teach that in the condition of cellulite, a reduction in local blood supply to the tissues results from increased pressure on the tissues due to upwards pressure from excess underlying adipose tissue, as well as, from deposition of plaque-like substances that clog the arterioles and venous capillaries. The increased blood perfusion flushes the capillaries and arterioles, resupplying the tissues with needed, newly oxygenated blood, and enhancing lymphatic drainage [0049].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the a vasoactive agent visnadine from Bertini Curri et al to treat cellulite in Di Pierro since Bertini Curri et al teach visnadine is used for cosmetic treatment of defects due to insufficient blood perfusion and as evidenced by Smith et al, cellulite is due to a reduction in local blood supply and deposition of plaque-like substances that clog the arterioles and venous capillaries. Therefore, one of ordinary skill in the art would have been motivated to use the vasoactive agent visnadine from Bertini Curri et al to let the increased blood perfusion flushes the capillaries and arterioles, and resupplying the cellulite tissues with needed, newly oxygenated blood, and enhancing lymphatic drainage so as to enhance the treatment of cellulite of Di Pierro.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that it is deemed that the prior art product must not be precluded for use as a vasoactive agent. It is deemed that the composition disclosed by Di Pierro and Bertini Curri et al is not precluded for carrying out the intended function of the claims.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments regarding the cited references do not visnadin have been fully considered and are persuasive. Therefore, the previous 103 rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Bertini Curri et al and Smith, III et al. Applicant's arguments with respect to Thiolon have been considered but are moot in view of the new ground(s) of rejection.

Regarding Di Pierro reference, Applicant argues that DI PIERRO requires at least a combination 4 vasoactive ingredients (plus one optional):

a) complex of escin/beta-sitosterol with phospholipids.

b) complex of *Gingko biloba* dimeric flavonoids with phospholipids,

c) complex of Centella asiatica triterpenes with phospholipids,

and optionally one or both of:

d) ethylximeninate, and

e) standardized *Coleus forskolli* extract (page 10, 1st paragraph).

This is not found persuasive. DI PIERRO only contains 3 vasoactive ingredients not including the optional ingredients. Since claim 1 recites "the third vasoactive agent is at least one compound selected from the group consisting of …escin beta-sitosterol complexed with phosphollipid, …the Centella asiatica extract", thus the third vasoactive ingredient is allowed to have more than two compounds. Therefore, DI PIERRO only teaches the second vasoactive agent and the third vasoactive agent. In addition, optional compound should not be considered since it is optional the composition only contains the basic components. Further more, claim 1 recites "A pharmaceutical, cosmetic, dieteric or nutraceutical composition comprising…", and

the open language "comprising" does not preclude any additional components that are not being claimed.

Applicant further argues that" There is no suggestion to select only one or two ingredients out of the list and combine the same with other active substances to produce a composition able to prevent cellulite. That is, the claimed invention includes a combination of vascoactive ingredients consisting of a first, second and third component" (page 10, 2nd paragraph).

Applicant argues that there is no specific suggestion or teaching in the reference to combine vascoactive ingredients. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods, which is to treat cellulite, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention. In addition, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20 (Bd. Pat. App.& Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655